

REMARKS

Claims 1-165 are pending the application. Claims 124, 126, and 127 were amended. Claim 124 was amended to incorporate the limitations of claim 125 (now canceled). Claims 126 and 127 were amended to reflect proper dependency from claim 124. Applicants submit that no new matter has been added to the claims.

The Examiner has restricted the prosecution of the application to one of the following groups of claims:

Group I, claim(s) 1-39, drawn to a method of detecting inflammation in a subject.

Group II, claim(s) 40-67, drawn to a method of detecting inflammation in a transplant, post transplantation.

Group III, claim(s) 68-91, drawn to a method of monitoring inflammation in a subject with inflammatory or autoimmune disease.

Group IV, claim(s) 92-105, drawn to a method of identifying a vector capable of detecting inflammation.

Group V, claim(s) 106-123, drawn to a method of treating inflammatory disease, comprising detection of an expressed nucleic acid and modifying treatment upon detection.

Group VI, claim(s) 124-127 and 165, drawn to treating inflammation in a subject by administration of a complement modulator.

Group VII, claim(s) 124-127, 130-132, 134, and 152-165, drawn to treating inflammation in a subject by administration of a nucleic acid encoding a complement modulator.

Group VIII, claim(s) 128, drawn to a transgenic animal.

Group IX, claim(s) 129, drawn to a cell line comprising a vector with a reporter nucleic which is expressed under conditions of inflammation.

Group X, claim(s) 133, 135, 136, 142-145, 150, and 151, drawn to a nucleic acid encoding at least two repeats of ED1 and a linker.

Group XI, claim(s) 137-141, 146, and 147-149, drawn to a nucleic acid encoding SEQ ID NO: 8 with at least 80% identity.

Applicant hereby provisionally elects Group VII, as set forth in claims 124-127, 130-132, 134, and 152-165, with traverse. Regarding the election of species, the Restriction Requirement requires that one species be elected from among SCR 13-15, Crry, (as in claims 126-127) and a specific complement inhibitor specifically supported by the specification. In response, Applicants hereby elect a complement inhibitor specifically supported by the specification, namely SEQ ID NO: 9. SEQ ID NO: 9 is found in previously presented claim 165. As provided in the Amendment and Response filed November 20, 2008, support for this claim can be found at least on page 28, lines 13-34 of the instant specification.

Applicant respectfully requests that the restriction requirement and the election of species be reconsidered and withdrawn for at least two reasons:

- **The Restriction Requirement does not comply with M.P.E.P § 803**

Without conceding that the claims in the various Groups are not patentably distinct, Applicant respectfully asserts that the Action has not shown that a serious burden would be required to examine all of the pending claims of Groups VII and IX and X in the this application. Specifically, M.P.E.P § 803 provides:

If the search and examination of an application can be made without serious burden, the Examiner *must* examine it on the merits, even though it includes claims to distinct or independent inventions.
(Emphasis supplied.)

Thus, for a restriction to be proper, the Office Action must satisfy the following two criteria: (1) the existence of independent and distinct inventions (35 U.S.C. § 121); and (2) that the search and examination of the entire application cannot be made without serious burden. *See* M.P.E.P § 803.

The Office Action has not shown that the second requirement has been met. Specifically, the Office Action has not shown that it would be a serious burden to search and examine all of the groups together. Indeed, the Office Action has not even alleged that it would be a serious

burden to search and examine all of the groups together. Consequently, reconsideration and modification or withdrawal of the restriction is requested.

• **The Action does not meet its burden for establishing lack of unity of invention**

Without conceding that the claims in the various Groups are not patentably distinct, Applicant respectfully asserts that the Restriction Requirement does not meet the requisite burden for establishing a lack of unity of invention. Specifically, 37 C.F.R. § 1.475 provides that national stage applications shall relate to one invention or to a group of inventions so linked as to form a single general inventive concept. Such inventions possess unity of invention. PCT Rule 13.2 states that

[T]he requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

Thus, the requirement of a single inventive concept is fulfilled when there is a technical relationship within the claimed subject matter involving one or more of the same or corresponding special technical features, which define a contribution that the claimed subject matter makes over the prior art. Additionally, MPEP 1850 states that contributions over the prior art "should be considered with respect to novelty and inventive step."

Applicant also respectfully requests that the requirement for species election be reconsidered, as the Examiner has not shown that a serious burden would result if all the species are examined together. M.P.E.P. § 803 provides that "[i]f the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions." (*Emphasis added.*) Thus, for a restriction requirement to be proper, the Examiner must satisfy the following two criteria: (1) the existence of independent and distinct inventions (35 U.S.C. § 121) and (2) the search and examination of the entire application cannot be made without serious burden. *See*

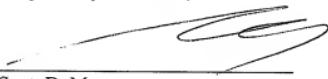
M.P.E.P. § 803. Applicant notes that the restriction requirement does not provide sufficient basis to indicate that examination of more than one of the "species" would overly burden the Examiner. Applicant thus respectfully requests reconsideration of the election requirement. Applicant reminds the Examiner that if the elected genus is found to be allowable, all of the species listed in claims 126-127 should also be found allowable.

Favorable consideration of claims 1-164 is earnestly solicited.

Pursuant to the above amendments and remarks, reconsideration and allowance of the pending application is believed to be warranted. The Examiner is invited and encouraged to directly contact the undersigned if such contact may enhance the efficient prosecution of this application to issue.

A credit card payment is being submitted via EFS Web in the amount of \$865.00, representing the fee for a small entity under 37 C.F.R. § 1.17(a)(4), together with a Request for Four Month Extension of Time. This amount is believed to be correct; however, the Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,



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CERTIFICATE OF ELECTRONIC TRANSMISSION UNDER 37 C.F.R. § 1.8			
I hereby certify that this correspondence, including any items indicated as attached or included, is being transmitted via electronic transmission via EFS-Web on the date indicated below.			
Name of Person Mailing (Print/Type)	Scott D. Marty		
Signature		Date:	7.17.09